

**REMARKS**

Favorable reconsideration is respectfully requested in view of the foregoing amendments and the following remarks.

**I. CLAIM STATUS AND AMENDMENTS**

Claims 9-24 were pending in this application when last examined.

Claims 9-10 were examined on the merits and stand rejected.

Claims 11-24 were withdrawn as non-elected subject matter.

Claim 10 is cancelled without prejudice or disclaimer thereto.

Applicants reserve the right to file a Continuation or Divisional Application on any cancelled or withdrawn subject matter.

Claim 9 is amended to clarify the claimed invention and to incorporate limitations of claim 10.

No new matter has been added.

**II. UTILITY /ENABLEMENT REJECTIONS**

On pages 2-3, claims 9-10 were rejected under 35 U.S.C. § 101 as lacking utility.

On page 4, claims 9-10 were also rejected under 35 U.S.C. § 112, first paragraph, as not enabled since no credible utility has been found.

Claim 10 is cancelled and therefore the rejections of this claim is moot.

Applicants respectfully traverse these rejections as applied to amended claim 9.

The Office's position is that the asserted utilities are not specific and substantial because the specification fails to disclose any particular function or biological significance for the sweat fraction.

Further, the Office contends that the specification does not disclose the identity of the sweat fraction responsible for the disclosed utilities.

Applicants note that the first full paragraph on page 16 of the specification indicates that it can be determined whether a patient has atopic dermatitis or is at high risk for developing atopic dermatitis by assaying whether the patient has an antibody in their serum that binds to the composition of claim 1. This is a substantial, specific and credible utility.

The Office further appears to indicate that because the claimed fraction has not been completely characterized then further research would be required to determine the usefulness of the fraction. However, Applicants note that the above-noted utility does not require any further characterization and therefore the claimed composition meets the utility requirement. Applicants also note that the claimed composition is a product-by-process claim which is permitted under US practice.

Applicants note that the composition of claim 1 has utility and therefore the 35 U.S.C. § 101 rejection should be withdrawn. Applicants further note that since a credible utility has been shown, the above-noted enablement rejection under 35 U.S.C. § 112, first paragraph, should be withdrawn.

### **III. INDEFINITENESS REJECTIONS**

On page 4, claim 9-10 were rejected under 35 U.S.C. § 112, second paragraph, as incomplete for omitting essential steps.

Claim 10 is cancelled and therefore the rejection of this claim is moot.

Applicants respectfully traverse this rejection as applied to amended claim 9.

The Office's position is that the structure of the recited compound is an essential step. Applicants respectfully disagree. Applicants note that claim 9 is a product-by-process claim as permitted under US practice. Applicants note that such claim can be seen as an extract, which are commonly granted patents. Thus, this rejection is untenable and should be withdrawn.

### **IV. ENABLEMENT REJECTION**

On pages 4-6, claims 9-10 were rejected under 35 U.S.C. § 112, first paragraph, for failing to meet the enablement requirement.

Claim 10 has been cancelled and therefore the rejection of this claim is moot.

Applicants respectfully traverse this rejection as applied to amended claim 9. Applicants note that in order to clarify the claimed invention and without acquiescence to the correctness of the Office's positions, claim 9 has been amended to indicate that the fraction activates mast cells and basophils upon binding to a human own IgE antibody and has atopic dermatitis inducing activity. Thus, as taught in the specification, such sweat can be obtained from a patient with atopic dermatitis. Thus, it is respectfully submitted that the claimed composition can be obtained

without undue experimentation and therefore this rejection, as applied to the amended claim, is untenable and should be withdrawn.

#### **V. WRITTEN DESCRIPTION REJECTION**

On pages 6-8, claims 9-10 were rejected under 35 U.S.C. § 112, first paragraph, for failing to meet the written description requirement.

Claim 10 is cancelled and therefore the rejection of this claim is moot.

Applicants respectfully traverse this rejection as applied to amended claim 9.

Again, Applicants note that the claims are product by process claims and do not require the structure of the claimed compound. Applicants further note that under the guidelines for examination of patent applications under the 35 U.S.C. § 112, paragraph one, "written description" requirement, the written description requirement for a claimed genus may be satisfied by disclosure of relevant, identifying characteristics such as physical properties. It is noted that the claimed product-by-process indicates that the claimed fraction activates mast cells and basophils upon binding to a human own IgE antibody and having an atopic dermatitis inducing activity. Further, the claimed product-by-process discloses a method of obtaining the claimed composition. Thus, Applicants note that the specification and the claim indicate that Applicants had possession of the claimed genus, i.e., a fraction with the noted properties that was obtained by the method recited in the claims.

Thus, for the above-noted reasons, this rejection is untenable and should be withdrawn.

#### **VI. ANTICIPATION REJECTION**

On pages 8-9, claims 9-10 were rejected under 35 U.S.C. § 102(b) as anticipated by Hide et al.

Claim 10 is cancelled and therefore the rejection of this claim is moot.

Applicants respectfully traverse this rejection as applied to amended claim 9.

Applicants note that Hide et al. describes on page 339, right column, lines 13-19 that "a dot blot study of these fractions did not show any apparent biding of serum IgE in sera of these patients." Since the composition of the claimed invention is able to bind IgE, this composition is clearly different from the composition of Hide et al.

For the above-noted reasons, this rejection is untenable and should be withdrawn.

**CONCLUSION**

In view of the foregoing amendments and remarks, it is respectfully submitted that the present application is in condition for allowance and early notice to that effect is hereby requested.

If the Examiner has any comments or proposals for expediting prosecution, please contact the undersigned attorney at the telephone number below.

Respectfully submitted,

Michihiro HIDE et al.

By:   
William R. Schmidt, II  
Registration No. 58,327  
Attorney for Applicants

WRS/lc  
Washington, D.C. 20006-1021  
Telephone (202) 721-8200  
Facsimile (202) 721-8250  
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